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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,264	12/19/2001	Binoy Appukuttan	D6124	5702

7590 07/29/2003

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EXAMINER
KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,264	APPUKUTTAN ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-10 are pending and are examined in this office action.

► *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm). Each amendment document that includes a change to an existing claim, or submission of a new claim,* ***must include a complete listing of all claims*** *in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a method of inhibiting intraocular cellular proliferation in an individual having age-related macular degeneration, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

II. Claims 1-4, drawn to a method of inhibiting intraocular cellular proliferation in an individual having proliferative diabetic retinopathy, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

III. Claims 1-4, drawn to a method of inhibiting intraocular cellular proliferation in an individual having retinopathy of prematurity, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

IV. Claims 1-4, drawn to a method of inhibiting intraocular cellular proliferation in an individual having glaucoma, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

V. Claims 1-4, drawn to a method of inhibiting intraocular cellular proliferation in an individual having proliferative vitreoretinopathy, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

VI. Claims 5-10, drawn to a method of inhibiting intraocular neovascularization in an individual having age-related macular degeneration, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

VII. Claims 5-10, drawn to a method of inhibiting intraocular neovascularization in an individual having proliferative diabetic retinopathy, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

VIII. Claims 5-10, drawn to a method of inhibiting intraocular neovascularization in an individual having retinopathy of prematurity, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

IX. Claims 5-10, drawn to a method of inhibiting intraocular neovascularization in an individual having glaucoma, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

X. Claims 5-10, drawn to a method of inhibiting intraocular neovascularization in an individual having proliferative vitreoretinopathy, by administering a lentiviral vector comprising a therapeutic gene classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-X are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant age-related macular degeneration, proliferative diabetic retinopathy, retinopathy of prematurity and glaucoma are diseases of different origin developed by different means, that requires different site of action to cure such anomalies. For example proliferative diabetic retinopathy is the result of high levels of sugar in blood, whereas glioma is the result of a genetic mutation that affect cell proliferation. In addition, inhibition of cell proliferation is distinct from inhibition of neovascularization. For instant inhibition of galioma cells can be achieved by targeting cancer specific mutant genes, whereas the inhibition of neovascularization can be achieved by modulating chemokine production, indicating diversity in the mode of action required for the treatment. Thus these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for other, restriction for examination purposes as indicated is proper. For example search of proliferative diabetic retinopathy would not be require for search required for the treatment of glioma.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 2 and 5 generic to a plurality of disclosed patentably distinct species comprising: retinoblastoma gene, p16 gene and p21 gene, tissue inhibitor of metalloproteinase (TIMP)-1, TIMP-2, TIMP-3, TIMP-4, endostatin, angiostatin, endostatin XVIII, endostatin XV, the C-terminal hemopexin domain of matrix metalloproteinase-2, the kringle 5 domain of human plasminogen, a fusion protein of endostatin and angiostatin, a fusion protein of endostatin and the kringle 5 domain of human plasminogen, the monokine-induced by interferon-gamma (Mig), the interferon-alpha inducible protein 10 (IP10), a fusion protein of Mig and IP10, soluble FLT-1 (fms-like tyrosine kinase 1 receptor), and kinase insert domain receptor (KDR). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
PATENT EXAMINER

SUMESH KAUSHAL
PATENT EXAMINER